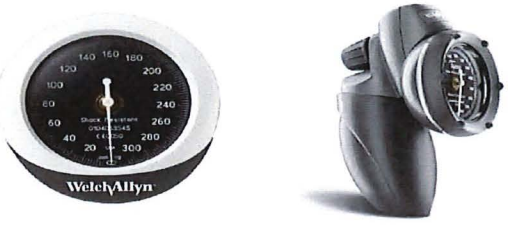
DECLARATION OF CONFORMITY

(in accordance with ISO/IEC 17050-1)

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

We declare, under our sole responsibility, that the product listed below conforms to the provisions of:

- European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Document Number 80016902	Version L	
Product Name	Welch Allyn Aneroid Sphygmomanometers	
Manufacturer's Name and Business Address	Welch Allyn, Inc. 4341 State Street Road Skaneateles Falls, NY 13153 USA	SRN: US-MF-000013394
EC Certificates Declaration of Conformity Validity	EC Certificate 314505 MR2 Expiry Date: 2024-05-26	
EC REP	Welch Allyn Limited Navan Business Park, Dublin Road Navan, Co. Meath, C15 AW22, Ireland	SRN: IE-AR-000000768
REF #	DS44, DS44A DS45, DS45A, DS45T DS48, DS48A DS58, DS-6501-300 DS-6601-300 DS-5401-300, DS-5402-300, DS-54L1-300, DS-54L2-300 DS-5501-300, DS-5502-300, DS-5511-300RMC, DS-5512-300RMC, DS-5521-300, DS-5541-300, DS-5561-300	
	901041 GAUGE, HAND HELD	
Radio equipment	N/A	
Object of the declaration	 Aneroid Sphygmomanometers	
Intended Purpose	N/A	

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Medical Device Conformity Assessment Route Annex	Annex II
Medical Device Classification	I(m)
Medical Device Classification Rule	1
Standards	See Appendix A
GMDN Code and Term	16156 Aneroid manual sphygmomanometer
UMDNS Code and Term	13102 Manometers
Notified Body	DQS Medizinprodukte GmbH, August-Schanz-Str.21, 60433 Frankfurt am Main Notified Body Number: 0297

Authorised Signatory

Megan Pellenz

Megan Pellenz
Regulatory Affairs Manager

2022-05-16
Date

Skaneateles Falls NY, USA
Place of Issue

Welch Allyn, Inc. is a subsidiary of Hill-Rom Holdings, Inc.

Appendix A: Standards and Common Specifications

Standards Applied	Number	Version/Date of Issue	Title
Directive 93/42/EEC	EN ISO 81060-1	2012	Non-invasive sphygmomanometers_- Part_1: Requirements and test methods for non-automated measurement type
	EN 62366-1	2015	Medical devices_- Application of usability engineering to medical devices
	EN ISO 10993-1	2009	Biological evaluation of medical devices_- Part_1: Evaluation and testing within a risk management process
	EN ISO 14155	2011	Clinical investigation of medical devices for human subjects_- Good clinical practice
	EN ISO 15223-1	2016	Medical devices_- Symbols to be used with medical device labels, labelling and information to be supplied_- Part_1: General requirements
	EN ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes